



Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/524,668-Conf. #1541
				Filing Date	March 8, 2006
				First Named Inventor	Boris Fuks
				Art Unit	1641
				Examiner Name	C. L. Chin
Sheet	1	of	4	Attorney Docket Number	04227/100L791-US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	US 5,554,504	09-10-1996	Rutanen	
	2.	US 5,037,735	08-06-1991	Khanna et al.	
	3.	US 4,952,517	08-28-1990	Bahar	
	4.	US 5,252,459	10-12-1993	Tarcha et al.	
	5.	US 4,810,658	03-07-1989	Shanks et al.	
	6.	US 4,978,503	12-18-1990	Shanks et al.	
	7.	US 5,186,897	02-16-1993	Eason et al.	
	8.	US 5,968,758	10-19-1999	Fuks et al.	
	9.	US 5,891,722	04-06-1999	Fuks et al.	
	10.	US 5,156,952	10-20-1992	Litman et al.	
	11.	US 5,030,558	07-09-1991	Litman et al.	
	12.	US 5,137,808	08-11-1992	Ullman et al.	
	13.	US 4,857,453	08-15-1989	Ullman et al.	
	14.	US 4,981,768	01-01-1991	Monbaliu et al.	
	15.	US 4,806,312	02-21-1989	Greenquist	
	16.	US 5,114,673	05-19-1992	Berger et al.	
	17.	US 4,632,901	12-30-1986	Valkirs et al.	
	18.	US 4,366,241	12-28-1982	Tom et al.	
	19.	US 4,770,853	09-13-1988	Bernstein	
	20.	US 4,313,734	02-02-1982	Leuvering	
	21.	US 4,373,932	02-15-1983	Gribnau et al.	
	22.	US 4,703,017	10-27-1987	Campbell et al.	
	23.	US 3,817,837	06-18-1974	Rubenstein et al.	
	24.	US 4,906,439	03-06-1990	Grenner	
	25.	US 4,918,025	04-17-1990	Grenner	
	26.	US 5,051,237	09-24-1991	Grenner et al.	
	27.	US 5,138,868	08-18-1992	Long	
	28.	US 5,141,871	08-25-1992	Kureshy et al.	
	29.	US 5,147,609	09-15-1992	Grenner	
	30.	US 5,352,582	10-04-1994	Lichtenwalter et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear
		Country Code ² -Number ³ -Kind Code ⁴ (if known)			
	31.	EP-B 0 362 809	04-11-1990	Corti et al.	
	32.	EP-A 0 143 574	06-05-1985	Zuk	
	33.	EP-A 0 299 428	01-31-1996	Ching et al.	
	34.	WO 88/08534	11-03-1988	May et al.	
	35.	EP-A 0 280 559	10-20-1993	Snyder	
	36.	EP-A 0 281 327	06-30-1993	Snyder	

Examiner Signature		Date Considered	
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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	37.	Bohn, H. 1980. Protein Antigens of the Human Placenta. Proceedings of the Serno Symposia 35:23-34.	
	38.	Cubbage, Michael L., et al. 1989. Structure of the Human Chromosomal Gene for the 25 Kilodalton Insulin-Like Growth Factor Binding Protein. Molecular Endocrinology 3:35:846-851.	
	39.	Koninckx, P.R. et al. 1981. Prolactin Concentration in Vaginal Fluid: A New Method for Diagnosing Ruptured Membranes. British Journal of Obstetrics and Gynecology 88:607-610.	
	40.	Petrinin, D.D. et al. 1988. A Comparative Study of Four Human Placental Proteins in the Course of Pregnancy. 50-52.	
	41.	Seppälä, M. et al. 1994. Uterine endocrinology and paracrinology: insulin-like growth factor binding protein-1 and placental protein 14 revisited. Human Reproduction 9(5):917-925.	
	42.	Bell, Stephen C. and John W. Keyte. 1988. N-Terminal Amino Acid Sequence of Human Pregnancy-Associated Endometrial α_1 -Globulin, an Endometrial Insulin-like Growth Factor (IGF) Binding Protein – Evidence for Two Small Molecular Weight IGF Binding Proteins. Endocrinology 123(2):1202-4.	
	43.	Bell, Stephen C. et al. 1991. Regulation of Insulin-Like Growth Factor-Binding Protein-1 Synthesis and Secretion by Progesterone and Relaxin in Long Term Cultures of Human Endometrial Stromal Cells. Journal of Clinical Endocrinology and Metabolism 72(5):1014-1024.	
	44.	Bischof, Paul. 1989. The Pregnancy Proteins (PP12, PP14 and PAPP-A): Their Biological and Clinical Relevance. American Journal of Perinatology 6(2):110-116.	
	45.	Rutanen, E-M. et al. 1988. Monoclonal Antibodies to the 27-34K Insulin-like Growth Factor Binding Protein. Biochemical and Biophysical Research Communications 152(1):208-215.	
	46.	Rutanen, E-M. et al. 1993. Measurement of insulin-like growth factor binding protein-1 in cervical/vaginal secretions: comparison with the ROM-check Membrane Immunoassay in the diagnosis of ruptured fetal membranes. Clinica Chimica Acta 214:73-81.	
	47.	Rutanen, E-M. et al. 1996. Evaluation of a rapid strip test for insulin-like growth factor binding protein-1 in the diagnosis of ruptured fetal membranes. Clinica Chimica Acta 253:91-101.	
	48.	Allander, S.V. et al. 1993. Gene Structures and Expressions. Growth Regulation 3(1):3-5.	
	49.	Bell, Stephen C. et al. 1989. Monoclonal Antibodies to Human Secretory "Pregnancy-Associated Endometrial α_1 -Globulin," an Insulin-Like Growth Factor Binding Protein: Characterization and Use in Radioimmunoassay, Western Blots, and Immunohistochemistry. American Journal of reproductive Immunology 20:87-96.	
	50.	Bohn, H. and W. Kraus. 1980. Isolation and Characterization of a New Placenta Specific Protein (PP ₁₂). Arch. Gynecol. 229:279-291.	
	51.	Busby, W.H. Jr. et al. 1988. Purification of a 31,000-dalton insulin-like growth factor binding protein from human amniotic fluid. Isolation of two forms with different biologic actions. J. Biol. Chem. 263(28):14203-10.	
	52.	Darj, Elisabeth and Sven Lyrenas. 1998. Insulin-like growth factor binding protein-1, a quick way to detect amniotic fluid. Acta. Obstet. Gynecol. Scand. 77:295-297.	
	53.	Diamandi, Anastasia et al. 2000. Immunoassay of Insulin-Like Growth Factor-Binding Protein-3 (IGFBP-3): New means to Quantifying IGFBP-3 Proteolysis. Journal of Clinical Endocrinology and Metabolism 85(6):2327-2333.	

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54.	Ehrenborg, Ewa et al. 1992. Congiguous Localization of the Genes Encoding Human Insulin-like Growth Factor Binding Proteins 1(IGBP1) and 3(IGBP3) on Chromosome 7. <i>Genomics</i> 12(3):497-502.	
55.	Hellemans, P. et al. 1992. Preliminary results with the use of the ROM-check immunoassay in the early detection of rupture of the amniotic membranes. <i>European Journal of Obstetrics & Gynecology and Reproductive Biology</i> 43:173-179.	
56.	Jeurgens-Borst, Anneke J.C.M et al. 2002. Use of insulin like growth factor binding protein-1 in the diagnosis of ruptured fetal membranes. <i>European Journal of Obstetrics & Gynecology and Reproductive Biology</i> 102:11-14.	
57.	Kim, He-Seong et al. 1997. Identification of a family of low-affinity insulin-like growth factor binding proteins (IGFBPs): Characterization of connective tissue growth factor as a member of the IGFBP superfamily. <i>Proc. Natl. Acad. Sci. USA</i> 94(24):12981-6.	
58.	Kishida, Tatsuro et al. 1996. Diagnosis of premature rupture of the membranes in preterm patients, using an improved AFP kit: comparison with ROM-check and/or nitrazine test. <i>European Journal of Obstetrics & Gynecology and Reproductive Biology</i> 69:77-82.	
59.	Koistinen, Riitta et al. 1986. Placental Protein 12 Is a Decidual Protein that Binds Somatomedin and Has an Identical NK-Terminal Amino Acid Sequence with Somatomedin-Binding Protein from Human Amniotic Fluid. <i>Endocrinology</i> 118(4):1375-1378.	
60.	Kubota, Takeyoshi and Hisaya Takeuchi. 1998. Evaluation of Insulin-Like Growth Factor Binding Protein-1 as a Diagnostic Tool for Rupture of the Membranes. <i>J. Obstet. Gynaecol. Res.</i> 24(6):411-417.	
61.	Lockwood, Charles J. et al. 1994. Fetal membrane rupture is associated with the presence of insulin-like growth factor-binding protein-1 in vaginal secretions. <i>Am. J. Obstet. Gynecol.</i> 171(1):146-50.	
62.	Lockwood, Charles J. et al. 1991. Fetal Fibronectin in Cervical and Vaginal Secretions as a Predictor of Preterm Delivery. <i>New England Journal of Medicine</i> 325(1):669-674.	
63.	Luthman, Holger et al. 1989. Human insulin-like growth-factor-binding protein. Low-molecular-mass form: protein sequence and cDNA cloning. <i>Eur. J. Biochem.</i> 180:259-265.	
64.	Marinaro, Joe A. et al. O-glycosylation delays the clearance of human IGF-binding protein-6 from the circulation. <i>European Journal of Endocrinology</i> 142:512-516.	
65.	Ooi, Guck T. et al. 1990. Recognition of insulin-like-growth-factor-binding proteins in serum and amniotic fluid by an antiserum against a low-molecular-mass insulin-like-growth-factor-inhibitor/binding protein. <i>Biochem. J.</i> 267:615-620.	
66.	Povoa, Guilherme. 1984. Cross-reaction of serum somatomedin-binding protein in a radioimmunoassay developed for somatomedin-binding protein isolated from human amniotic fluid. <i>Acta Endocrinologica</i> 107:563-570.	
67.	Ragosch, V. et al. Insulin like growth factor binding protein 1 (IGFBP-1). <i>Geburtsh. U. Frauenheilk.</i> 56:291-296.	
68.	Rosenfeld, Ron. G. et al. 1999. The Insulin-like Growth Factor Binding Protein Superfamily: New Perspectives. <i>Pediatrics</i> 104:1018-1021.	
69.	Rutanen, Eeva-Marja and Fredrika Pekonen. 1991. Diagnosis of Premature Rupture of Fetal Membranes by the Measurement of Insulin-like Growth Factor Binding Protein-1 in Cervical Secretion. <i>Am. J. Obst. Syn.</i> 164(1) Abstract 38:258.	
70.	Seppala, Markku et al. 1983. Immunologic and Biological Properties and Clinical Significance of Placental Proteins PP5 and PP12. <i>Annals New York Academy of Sciences</i> 417:368-382.	

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71.	Woltmann, Wiebke et al. 1995. Detection of Ruptured Fetal Membranes using Insulin-like Growth Factor-binding Protein-1. Z. Geburtsh. Neonatol. 199:243-244.	
72.	Zaraysky, E.I. et al. 1989. Immunoenzyme Assay of Placenta Specific α_1 -Microglobulin in Donor Blood Serum. Voprosy Med. Khimii 5:130-132.	
73.	Rochelson, Burton L. et al. 1987. A Rapid Colorimetric AFP Monoclonal Antibody Tet for the Diagnosis of Preterm Rupture of the Membranes. Obstetrics & Gynecology 69(2):163-163.	
74.	Medix Biochemica. 2006. Actim PROM (product information).	
75.	Ballard, F.J. et al. 1990. Report on the Nomenclature of the IGF Binding Proteins. Journal of Clinical Endocrinology and Metabolism 70(3):817.	
76.	Berggard, Tord. 1998. Structure and distribution of alpha-1-microglobulin proteins. Lund University Doctoral Dissertation (abstract).	

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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